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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,052	08/07/2003	Norman Krause	CMV-005.03 (23650-503)	1022

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/636,052	KRAUSE ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) *3 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Amendment filed 10/24/2008 is acknowledged. Claim 2 is canceled. Claims 1,3-20 are pending. Claims 3,17-20 remain withdrawn from consideration. Claims 1, 4-16 are under examination.

Applicant's arguments have been fully considered and were deemed to be persuasive-in-part. Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 U.S.C. § 101 (non-statutory invention) (New rejection)

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1, 4-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 4-16 are drawn to method of generating a surgical plan.

To qualify as a statutory process, the claims should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject mater that is being transformed, for example by identifying the material that is being changed to a different state or thing. In the instant case, claims do not recite any physical transformation step. Further, there is no step in the claims that recites a tie to another category of invention. Therefore, the claims are drawn to non-statutory subject mater for failing to recite a step that ties the method to another category of invention.

A claimed process is patent-eligible under § 101 if it is tied to a particular machine or apparatus, or it transforms a particular article into a different state or thing. Thus, the machine-or-transformation test is a two-branched inquiry: an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. See In re Bilski (Fed. Cir., October 30, 2008). The use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility. Further, the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.

Applicants' process is neither tied to a particular machine or apparatus, nor it transforms a particular article into a different state or thing. Thus, the claims fail the machine-or-transformation test and is not drawn to patent-eligible subject matter.

Further, there is no practical application to produce a real-world result as a result of the method as claimed. A tangible result requires that the claim must set forth a practical application to produce a real-world result. In the instant case, there is no tangible output of a result of the claimed method – the steps such as "generating", "associating", "updating", etc. can take place entirely within confines of a computer (or human brain) without an output to a user.

Claim Rejections - 35 USC § 103

3. Claims 1,2,4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleute et al. (Nonrigid 3-D/2-D Registration of Images Using Statistical Models . In Proceedings of MICCAI. 1999, 138-147) in view of DiGioia et al (Computer Assisted Orthopaedic Surgery. Image Guided and Robotic Assistive Technologies. Clinical Orthopaedics, 1995, 354, p. 31-39; reference in IDS) and Background art (specification, p. 4).

The instant claims are drawn to method of generating an updated surgical plan, the method comprising:

- generating a three dimensional (3D) model of a bone, based on the 2D images and bone template(s),
- generating a surgical plan including:

- one or more locations on the bone upon which to dispose one or more fixators, and

- one or more settings of one or more struts of the one or more fixators, and

- based on data associated with the placement of the one or more fixators disposed on the bone, generating an updated surgical plan including updated settings for one or more of the one or more struts

Claim 4 specifies that locations on the bone are locations for pins for fixators. Further, claims 7-10 specify that the data of locations are based on one or more images of fixators (claim 8), such as X-ray images (claim 10), which can be orthogonal to each other (claim 9)

Claim 5 specifies that settings of struts include one or more periodic adjustments of the struts

Fleute et al. teach that since the introduction of computed tomography surgical interventions are preceded by the construction of a CT-based 3D model of the object of interest to provide the surgeon with spatial information which is missing when using only 2D images. p. 138. Fleute et al. teach algorithm for generation of three dimensional model of a bone by reconstruction of 3D shapes using x-ray views and a statistical model. 3-D model of the patient bones is constructed by deforming a statistical 3-D model to the contours segmented on the x-ray views. The statistical model (template) is made of a few principal modes that are sufficient to represent the normal anatomy. Fitting the template to the segmented 2D x-ray contours of the bone is achieved by using iterative closest point algorithm to non-rigid 3D/2D registration. See Abstract and pages 143-147. Thus, the reference teaches obtaining bone model as claimed.

The reference does not teach using the described 3D model of a bone to generate a particular surgical plan for bone distraction that includes such considerations as locations on the bone where to dispose fixators, or settings of struts of fixators.

DiGioia et al teach that planning of orthopedic surgery benefits from use of computer assisted planning tools comprising imaging capabilities. (See also references discussed in Background Section of the instant application, pages 7,8). Thus, the reference teaches:

> …Once the optimal plan is developed, surgeons will be able to implement that plan accurately and precisely. Only by coupling preoperative medical images and optimized plans with accurate tools used during surgery will the full potential of these new technologies be realized.
>
> Image guided surgical navigational tools also will provide clinical researchers with a new generation of measurement devices and intraoperative sensors which will permit the quantification of current clinical practice and provide information about surgical procedures and techniques never before available during surgery. Such quantification of intra- operative variables then can be used to analyze and validate more precisely long term clinical outcomes

As disclosed in the Background section of the instant specification, with respect to bone distraction process,

> At present, the following nominal steps are performed during the bone distraction process: (1) Determine an appropriate frame size for the fixator (e.g., for the Ilizarov fixator 20); (2) Measure (e.g., from X-rays) the deformity of bone fragments (or the anticipated fragments after surgically cutting the bone) and obtain six parameters that localize one fragment relative to the other; (3) Determine (or anticipate) how the fixator frame should be mounted on the limb; (4) Input the parameters and measurements to a computer program that generates the strut lengths as a function of time required to correct the deformity; (5) Mount the fixator frame onto the bone fragments; and (6) Adjust the strut lengths on a daily basis according to the schedule generated in step (4).
>
> The steps outlined in the preceding paragraph are currently executed with minimal computerized assistance. Typically, surgeons manually gather or determine the required data (e.g., fixator frame size, bone dimensions, fixator frame mounting location and orientation, etc.) and make their decisions based on hand-drawn two-dimensional sketches or using digitized drawings obtained by tracing X-ray images.

In *KSR Int 'l v. Teleflex*, the Supreme Court, in rejecting the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, indicated that

> The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007).

Applying the KSR standard of obviousness to Fleute et al, DiGioia and art disclosed in the Background section, Examiner concludes that the combination of the references is an obvious use of known technique to improve similar methods. The nature of the problem to be solved, effective preparation of surgical plan for bone distraction surgery, may lead inventors to look at references relating to possible improvements, such as use of computer assisted planning tools comprising imaging capabilities comprising three-dimensional, rather than two dimensional, model of a bone. Therefore, it would have been obvious to gather or determine the required information such as fixator frame mounting location and orientation, frame size, bone dimensions, etc., and make their decisions based on computational method of generating 3D model of a bone. Using the known technique of generating 3D model of a bone to provide necessary information for preoperative planning of bone distraction surgery would have been obvious to one of ordinary skill.

With respect to dependent claims 4-6,11-13 , if there are any differences between Applicant's claimed method and that of the prior art, the differences would be appear minor in nature. Although the prior art do not teach the various details of plan development and evolution, it would be conventional and within the skill of the art to select and/or determine all necessary conditions for the intended purpose of quality planning of successful bone distraction procedure and selection of appropriate conditions for fixator frame mounting location and orientation, frame size, bone dimensions, etc., as well as generation of surgical procedure using simulated computer animation, are conventional and within the skill in the art to which this invention pertains.

4. Claims 1,4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso (US 6,112,109; reference in IDS) in view of DiGioia et al (Computer Assisted Orthopaedic Surgery. Image Guided and Robotic Assistive Technologies. Clinical Orthopaedics, 1995, 354, p. 31-39; reference in IDS) and Background art (specification, p. 4).

Applicant's arguments with regard to the rejection over D'Urso have been fully considered and were deemed to be persuasive-in-part. The following rejection is therefore revised to address the issue of using templates to generate a 3D bone model.

The instant claims are drawn to method of generating an updated surgical plan as described in the preceding rejection.

D'Urso discloses a method of constructing/modeling of a three-dimensional image of anatomical features such as bone by determining one or more contours of the

bone based on one or more two-dimensional images or 2D projections of the bone. The contour of the bone is based on modifying 3D template model of the bone to generate a 3D model of the bone (col. 5, lines 11-33). D'Urso discloses that the 2D image data is digitized X-ay images (col. 5, lines 34-36). Using conventional computer software the data relating to the reconstructed two dimensional images is computed and interpolated by voxel or contour means to generate three dimensional coordinate data sets Col. 8, lines 20-38.

D'Urso does not teach use of 3D bone templates in reconstructing 3D data set.

Fleute et al. teach algorithm for generation of three dimensional model of a bone by reconstruction of 3D shapes using x-ray views and a statistical model. 3-D model of the patient bones is constructed by deforming a statistical 3-D model to the contours segmented on the x-ray views. The statistical model (template) is made of a few principal modes that are sufficient to represent the normal anatomy. Fitting the template to the segmented 2D x-ray contours of the bone is achieved by using iterative closest point algorithm to non-rigid 3D/2D registration. See Abstract and pages 143-147. Thus, the reference teaches obtaining bone model as claimed.

It would be obvious to use 3D bone templates as described in Fleute in reconstructing 2D bone contours in the method of D'Urso as it facilitates and enhances the reconstruction as discussed in Fleute.

Further, the combination of references does not specifically teach using the 3D model of a bone to generate a particular surgical plan for bone distraction that includes such considerations as locations on the bone where to dispose fixators, or settings of struts of fixators.

DiGioia et al teach that planning of orthopedic surgery benefits from use of computer assisted planning tools comprising imaging capabilities. (See also references discussed in Background Section of the instant application, pages 7,8). Thus, the reference teaches:

> …Once the optimal plan is developed, surgeons will be able to implement that plan accurately and precisely. Only by coupling preoperative medical images and optimized plans with accurate tools used during surgery will the full potential of these new technologies be realized.
>
> Image guided surgical navigational tools also will provide clinical researchers with a new generation of measurement devices and intraoperative sensors which will permit the quantification of current clinical practice and provide information about surgical procedures and techniques never before available during surgery. Such quantification of intra- operative variables then can be used to analyze and validate more precisely long term clinical outcomes

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> The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in

the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

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With respect to dependent claims 4-6,11-13 , if there are any differences between Applicant's claimed method and that of the prior art, the differences would be appear minor in nature. Although the prior art do not teach the various details of plan development and evolution, , it would be conventional and within the skill of the art to select and/or determine all necessary conditions for the intended purpose of quality planning of successful bone distraction procedure and selection of appropriate

conditions for fixator frame mounting location and orientation, frame size, bone dimensions, etc., as well as generation of surgical procedure using simulated computer animation, are conventional and within the skill in the art to which this invention pertains.

Prior art made of record

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure

Tanaka et al (US 6692448) teach an artificial bone template selection system which includes a template data storage system in which template data representing a plurality of templates representing a plurality of artificial bones of different shapes is stored.

Coquillart et al (reference provided by applicant) describes free form deformation technique for 3D modeling which uses templates for #D reconstruction of 2D images.

US 5408409 is directed to a surgical planning system, comprising:

means for inputting first data specifying cross-sectional images of a region of tissue into which a device is to be implanted;
means for inputting second data specifying a three dimensional representation of the device; and
data processor means, responsive to inputs from an operator of the system and to the first data and the second data, for interactively superimposing a cross-sectional image of the three dimensional representation of the device to be implanted .

Conclusion.

6. No claims are allowed

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571)272-0720 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./
Primary Examiner, Art Unit 1631